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1644

PATENT
Attorney Docket No. LEX-011

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Gillies et al.
SERIAL NO.: 09/780,668 GROUP NO.: 1644
FILING DATE: February 9, 2001 EXAMINER: David A. Saunders
TITLE: Enhancing the Circulating Half-Life of Antibody-Based Fusion Proteins

CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 24th day of February, 2004.

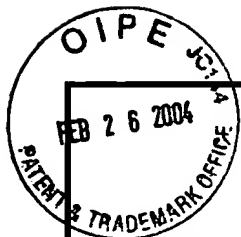

Anna-Karin Kuliga

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith is/are:

1. Transmittal Form (1 page);
2. Second Supplemental Information Disclosure Statement (2 pages);
3. Form PTO-1449 (8 pages);
4. Copies of cited references (A60-A96, B92-B106 and C171-C240); and
5. return receipt postcard.



TRANSMITTAL FORM

Application Serial Number	09/780,668
Filing Date	February 9, 2001
First Named Inventor	Gillies
Group Art Unit	1644
Examiner Name	David A. Saunders
Attorney Docket No.	LEX-011
Patent No.	Not applicable
Issue Date	Not applicable


ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Check Attached <input type="checkbox"/> Copy of Fee Transmittal Form	<input type="checkbox"/> Copy of Notice to File Missing Parts of Application <input type="checkbox"/> Formal Drawing(s)	<input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences <input type="checkbox"/> Appeal Brief (in triplicate)
<input type="checkbox"/> Amendment/Response <input type="checkbox"/> Preliminary <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ____]	<input type="checkbox"/> Request For Continued Examination (RCE) Transmittal <input type="checkbox"/> Power of Attorney (Revocation of Prior Powers) <input type="checkbox"/> Terminal Disclaimer	<input type="checkbox"/> Status Inquiry <input checked="" type="checkbox"/> Return Receipt Postcard <input checked="" type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8 <input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8
<input type="checkbox"/> Petition for Extension of Time	<input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application	<input type="checkbox"/> Additional Enclosure(s) (please identify below)
<input checked="" type="checkbox"/> Second Supplemental Information Disclosure Statement <input checked="" type="checkbox"/> Form PTO-1449 <input checked="" type="checkbox"/> Copies of IDS Citations	<input type="checkbox"/> Small Entity Statement <input type="checkbox"/> CD(s) for large table or computer program	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> Amendment After Allowance	
<input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above	<input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate)	

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Respectfully submitted,

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PATENT
Attorney Docket No. LEX-011

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Gillies et al. CONFIRMATION NO.: 8264
SERIAL NO.: 09/780,668 GROUP NO.: 1644
FILING DATE: February 09, 2001 EXAMINER: David A. Saunders
TITLE: ENHANCING THE CIRCULATING HALF-LIFE OF ANTIBODY-BASED
FUSION PROTEINS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**

- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

Applicants believe no fee is required for entry and consideration of this paper. If a fee is required, please charge Deposit Account 20-0531.

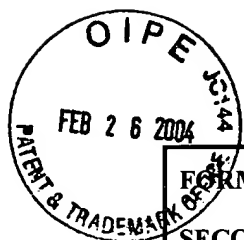
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FORM PTO - 1449

SECOND SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-011

APPLICANT(S): Gillies *et al.*

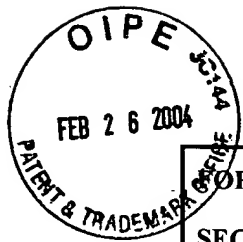
SERIAL NO.: 09/780,668

EXAMINER: David A. Saunders

FILING DATE: February 9, 2001 GROUP: 1644

U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A60	4,703,008	10/27/87	Lin	435	240.2	11/30/84
	A61	5,457,038	10/10/95	Trinchieri et al.	435	69.52	9/18/90
	A62	5,441,868	8/15/95	Lin	435	69.4	10/23/87
	A63	5,547,933	8/20/96	Lin	514	8	6/7/95
	A64	5,618,698	4/8/97	Lin	435	69.4	6/6/95
	A65	5,650,150	7/22/97	Gillies	424	134.1	7/27/94
	A66	5,688,679	11/18/97	Powell	435	240.2	10/6/93
	A67	5,723,125	3/3/98	Chang et al.	424	134.1	9/25/96
	A68	5,756,349	5/26/98	Lin	435	325	6/6/95
	A69	5,908,626	6/1/99	Chang et al.	424	134.1	12/19/97
	A70	5,955,422	9/21/99	Lin	514	8	8/2/93
	A71	6,100,387	8/8/00	Herrmann et al.	536	23.4	2/28/97
	A72	6,231,536	5/15/01	Lentz	604	5.04	5/21/99
	A73	6,284,536	9/4/01	Morrison et al.	435	328	4/20/99
	A74	6,335,176 B1	1/1/02	Inglese et al.	435	7.72	10/16/98
	A75	6,340,742	1/22/02	Burg et al.	530	351	6/28/00
	A76	6,444,792	9/3/02	Gray et al.	530	387.3	1/8/99
	A77	6,475,717 B1	11/5/02	Enssle et al.	435	5	7/25/97
	A78	6,485,726 B1	11/26/02	Blumberg et al.	424	178.1	7/24/98
	A79	6,506,405	1/14/03	Desai et al.	424	450	8/1/00
	A80	6,583,272	6/24/03	Bailon	530	397	6/27/00
	A81	6,586,398	7/1/03	Kinstler et al.	514	12	4/7/00
	A82	6,617,135	9/9/03	Gillies et al.	435	69.7	8/9/00
	A83	2001/0053539 A1	12/20/01	Lauffer et al.	435	69.1	4/6/99
EXAMINER					DATE CONSIDERED		



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U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A84	2002/0081664 A1	6/27/02	Lo et al.	435	69.5	10/11/01
	A85	2002/0142374 A1	10/3/02	Gallo et al.	435	69.1	8/17/99
	A86	2002/0147311 A1	10/10/02	Gillies et al.	530	387.1	2/9/01
	A87	2002/0192222 A1	12/19/02	Blumberg et al.	424	178.1	8/8/02
	A88	2002/0193570 A1	12/19/02	Gillies et al.	530	351	12/4/01
	A89	2003/0003529 A1	1/2/03	Bayer	435	68.1	7/19/02
	A90	2003/0044423 A1	3/6/03	Gillies et al.	424	192.1	3/7/02
	A91	2003/0049227 A1	3/13/03	Gillies et al.	424	85.1	6/29/01
	A92	2003/0105294 A1	6/5/03	Gillies et al.	530	351	2/24/99
	A93	2003/0012789 A1	1/6/03	Blumberg et al.	424	145.1	8/8/02
	A94	2003/0157054 A1	8/21/03	Gillies et al.	424	85.1	5/3/02
	A95	2003/0166163 A1	9/4/03	Gillies	435	69.52	12/4/02
	A96	2003/0166877 A1	9/4/03	Gillies et al.	530	395	3/29/02

EXAMINER

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FOREIGN PATENT DOCUMENTS

EXAM INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B92	1 088 888 A1	4/04/01	EP			5/13/99	N	Y
	B93	WO 96/18412	6/20/96	PCT			12/12/94	N	Y
	B94	WO 97/00319	1/03/97	PCT			6/11/96	N	Y
	B95	WO 99/43713	9/02/99	PCT			2/24/99	N	Y
	B96	WO 00/24893	5/04/00	PCT			10/18/99	N	
	B97	WO 01/36489 A2	5/25/01	PCT			11/03/00	N	Y
	B98	WO 01/58957 A2	8/16/01	PCT			2/09/01	N	Y
	B99	WO 02/02143 A2	1/10/02	PCT			06/29/01	N	Y
	B100	WO 02/066514 A2	8/29/02	PCT			2/18/02	Y	Y
	B101	WO 02/072605 A2	9/19/02	PCT			3/07/02	N	Y
	B102	WO 02/079232 A2	10/10/02	PCT			3/30/02	N	Y
	B103	WO 02/079415 A2	10/10/02	PCT			3/29/02	N	Y
	B104	WO 02/090566 A2	11/14/02	PCT			5/03/02	N	Y
	B105	WO 03/048334 A2	6/12/03	PCT			12/04/02	N	Y
	B106	WO 03/077834 A2	9/25/03	PCT			7/03/02	N	Y

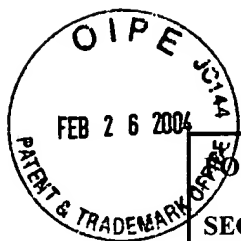
EXAMINER

DATE CONSIDERED



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		FILING DATE: February 9, 2001 GROUP: 1644	
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)		
	C171	Angal et al., (1993), "A Single Amino Acid Substitution Abolishes the Heterogeneity of Chimeric Mouse/Human (IgG4) Antibody," <u>Molecular Immunology</u> , 30:105-108.	
	C172	Batova et al., (1999), "The Ch 14.18-GM-CSF Fusion Protein Is Effective at Mediating Antibody-dependent Cellular Cytotoxicity and Complement-dependent Cytotoxicity in Vitro," <u>Clinical Cancer Research</u> , 5:4259-4263.	
	C173	Becker et al., (1996), "Long-lived and transferable tumor immunity in mice after targeted interleukin-2 therapy," <u>J Clin Invest.</u> , 98(12):2801-4.	
	C174	Becker et al., (1996), "T Cell-mediated eradication of murine metastatic melanoma induced by targeted interleukin 2 therapy," <u>J Exp Med.</u> , 183(50):2361-6.	
	C175	Bitonti et al., (2002), "Transepithelial Absorption of an Erythropoietin-Fc Fusion Protein After Delivery to the Central Airways," <u>Respiratory Drug Delivery</u> , 8:309-312.	
	C176	Briggs et al., (1974), "Hepatic Clearance of Intact and desialylated Erythropoietin," <u>American Journal of Physiology</u> , 227:1385-1388.	
	C177	Chuang et al., (1994), "Alteration of Lymphocyte Microtubule Assembly, Cytotoxicity, and Activation by the Anticancer Drug Taxol," <u>Cancer Research</u> , 54:1286-1291.	
	C178	Cruse et al., (1995), Illustrated Dictionary of Immunology, <u>CRC Press</u> , NY, p.156-7.	
	C179	Darling et al., (2002), "Glycosylation of Erythropoietin Affects Receptor Binding Kinetics: Role of Electrostatic Interactions," <u>Biochemistry</u> , 41:14524-14531.	
	C180	Davis et al., (2003), "Immunocytokines: amplification of anti-cancer immunity," <u>Cancer Immunol Immunother</u> 52:297-308	
	C181	Dolman et al., (1998), "Suppression of human prostate carcinoma metastases in severe combined immunodeficient mice by interleukin 2 immunocytokine therapy," <u>Clin Cancer Res.</u> , 4(10):2551-7.	
	C182	Duncan et al., (1988), "The binding site for C1q on IgG," <u>Nature</u> , 332:738-740.	
	C183	Egrie et al., (2001), "Development and characterization of novel erythropoiesis stimulating protein (NESP)," <u>Nephrol. Dial. Transplant.</u> , 16:3-13.	
	C184	Elliott et al., (1997), "Mapping of the Active Site of Recombinant Human Erythropoietin," <u>Blood</u> , 89(2):493-502.	
	C185	Fell et al., (1991), "Genetic Construction and Characterization of Fusion Protein Consisting of a Chimeric F(ab') with Specificity for Carcinomas and Human IL-2," <u>The J. of Immunology</u> , 146:7:2446-2452.	

EXAMINER	DATE CONSIDERED
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FORM PTO - 1449 SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		ATTORNEY DOCKET NO.: LEX-011 APPLICANT(S): Gillies <i>et al.</i> SERIAL NO.: 09/780,668 EXAMINER: David A. Saunders FILING DATE: February 9, 2001 GROUP: 1644
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C186	Fibi et al., (1995), "N- and O-Glycosylation Muteins of Recombinant Human Erythropoietin Secreted From BHK-21 Cells," <u>Blood</u> , 85:1229-1236.
	C187	Frost et al., (1997), "A Phase I/IB Trial of Murine Monoclonal Anti-GD2 Antibody 14.G2a plus Interleukin-2 Children with Refractory Neuroblastoma", <u>Cancer</u> , 80:317-33.
	C188	Gan et al., (1999), "Specific enzyme-linked immunosorbent assays for quantitation of antibody-cytokine fusion proteins," <u>Clin Diagn Lab Immunol.</u> , 6(2):236-42.
	C189	Gillies et al., (1991), "Expression of genetically engineered immunoconjugates of lymphotoxin and a chimeric anti-ganglioside GD2 antibody," <u>Hybridoma</u> , 10(3):347-56.
	C190	Gillies et al., (1999), "Improving the Efficacy of Antibody-Interleukin 2 Fusion Proteins by Reducing Their Interaction with Fc Receptors," <u>Cancer Research</u> , 59:2159-2166.
	C191	Gillies et al., (2002), "Bi-functional cytokine fusion proteins for gene therapy and antibody-targeted treatment of cancer," <u>Cancer Immunol Immunother.</u> , 51(8):449-60.
	C192	Gillies et al., (2002), "Improved circulating half-life and efficacy of an antibody-interleukin 2 immunocytokine based on reduced intracellular proteolysis," <u>Clin. Cancer Res.</u> , 8(1):210-6.
	C193	Greene et al., (1975), "Neuronal properties of hybrid neuroblastoma X sympathetic ganglion cells", <u>Proc. Natl. Acad. Sci. USA</u> , 72:4923-4927.
	C194	Hammerling et al., (1996), "In vitro bioassay for human erythropoietin based on proliferative stimulation of an erythroid cell line and analysis of carbohydrate-dependent microheterogeneity," <u>Journal of Pharmaceutical and Biomedical Analysis</u> , 14:1455-1469.
	C195	Hank et al., (2003), "Determination of peak serum levels and immune response to the humanized anti-ganglioside antibody-interleukin-2 immunocytokine," <u>Methods Mol Med.</u> , 85:123-31.
	C196	Haraguchi, (1994), "Isolation of GD3 synthase gene by expression cloning of GM3 α -2,8-sialyltransferase cDNA using anti-GD2 monoclonal antibody, <u>Proc. Natl. Acad. Sci. USA</u> , 91(22):10455-9.
	C197	Harris, (1995), "Processing of C-terminal lysine and arginine residues of proteins isolated from mammalian cell culture," <u>J. Chromatogr. A.</u> , 705:129-134.
	C198	Hezareh et al, (2001), "Effector function activities of a panel of mutants of a broadly neutralizing antibody against human immunodeficiency virus type 1," <u>J. Virol.</u> , 75(24):12161-8.
	C199	Idusogie et al., (2000), "Mapping of the C1q binding site on rituxan, a chimeric antibody with a human IgG1 Fc," <u>J. Immunol.</u> , 164(8):4178-84.
	C200	Imboden et al., (2001), "The level of MHC class I expression on murine adenocarcinoma can change the antitumor effector mechanism of immunocytokine therapy," <u>Cancer Res.</u> , 61(4):1500-7.

EXAMINER	DATE CONSIDERED
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FORM PTO - 1449

SECOND SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-011

APPLICANT(S): Gillies *et al.*

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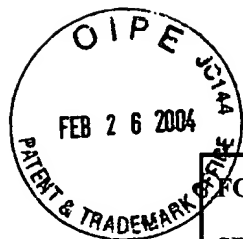
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	C201	Kato et al., (1997), "Mechanism for the Nonlinear Pharmacokinetics of Erythropoietin in Rats," <u>The Journal of Pharmacology and Experimental Therapeutics</u> , 283:520-527.
	C203	Kato et al., (1998), "Pharmacokinetics of Erythropoietin in Genetically Anemic Mice," <u>Drug Metabolism and Disposition</u> , 26:126-131.
	C204	Kendra et al., (1999), "Pharmacokinetics and Stability of the ch 14.18-Interleukin-2 Fusion Protein in Mice," <u>Cancer Immunol. Immunotherapy</u> , 48:219-229.
	C205	King et al., (2003), "A Phase I/IB clinical trial of the immunocytokine hu14.18-IL2 (EMD 273063) in patients with melanoma," Author's manuscript dated June 6, 2003.
	C206	Kitamura et al., (1989), "Establishment and Characterization of a Unique Human Cell Line that Proliferates Dependently on GM-CSF, IL-3, or Erythropoietin," <u>Journal of Cellular Physiology</u> , 140:323-334.
	C207	Kushner et al., (2001), "Phase II Trial of the Anti-GD2 Monoclonal Antibody 3F8 and Granulocyte-Macrophage Colony-Stimulating Factor for Neuroblastoma," <u>J. Clin. Oncol.</u> , 19:4189-94.
	C208	Locatelli et al., (2001), "Darbepoetin alfa Amgen," <u>Current Opinion in Investigational Drugs</u> , 2:1097-1104.
	C209	Lode et al., (1997), "Targeted interleukin-2 therapy for spontaneous neuroblastoma metastases to bone marrow," <u>J Natl Cancer Inst.</u> , 89(21):1586-94.
	C210	Lode et al., (2000), "What to do with targeted IL-2," <u>Drugs Today</u> , 36(5):321-36.
	C211	Lode et al., (2000), "Melanoma immunotherapy by targeted IL-2 depends on CD4(+) T-cell help mediated by CD40/CD40L interaction," <u>J. Clin. Invest.</u> , 105(11):1623-30.
	C212	Macdougall, (2002), "Optimizing the Use of Erythropoietic Agents—Pharmacokinetic and Pharmacodynamic Considerations," <u>Nephrol. Dial. Transplant.</u> , 17:66-70.
	C213	Metelitsa et al., (2002), "Antidisialoganglioside/granulocyte macrophage-colony-stimulating factor fusion protein facilitates neutrophil antibody-dependent cellular cytotoxicity and depends on FcγRII (CD32) and Mac-1 (CD11b/CD18) for enhanced effector cell adhesion and azurophil granule exocytosis," <u>Blood</u> , 99(11):4166-73.
	C214	Mueller et al., (1997), "Humanized porcine VCAM-specific monoclonal antibodies with chimeric IgG2/G4 constant regions block human leukocyte binding to porcine endothelial cells," <u>Molecular Immunology</u> , 34(6):441-452.
	C215	Mullins et al., (1997), "Taxol-mediated changes in fibrosarcoma-induced immune cell function: modulation of antitumor activities," <u>Cancer Immunol Immunother.</u> , 45:20-28.
	C216	Naramura et al., "Mechanisms of cellular cytotoxicity mediated by a recombinant antibody-IL2 fusion protein against human melanoma cells," <u>Immunol Lett.</u> , 39(1):91-9.

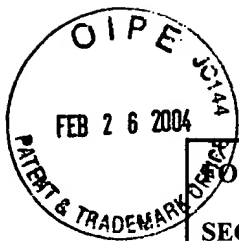
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	C217	Neal et al., (2003), "NXS2 murine neuroblastomas express increased levels of MHC class I antigens upon recurrence following NK-dependent immunotherapy," <u>Cancer Immunol Immunother.</u> , Pub. Med ID: 14504825.
	C218	Ngo et al., (1994), "Computational Complexity, Protein Structure Prediction, and the Levinthal Paradox" pp. 433-440 and 492-495.
	C219	Niethammer et al., (2001) "An oral DNA vaccine against human carcinoembryonic antigen (CEA) prevent growth and dissemination of Lewis Lung carcinoma in CEA transgenic mice," <u>Vaccine</u> , 20(3-4):421-9.
	C220	Niethammer et al., (2001) "Targeted Interleukin 2 therapy enhances protective immunity induced by an autologous murine melanoma," <u>Cancer Res.</u> , 61(16):6178-84.
	C221	Nimtz et al., (1993) Structures of Sialylated Oligosaccharides of Human Erythropoietin Expressed in recombinant BHK-21 Cells," <u>Eur. J. Biochem.</u> , 213:39-56.
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	C230	Spiekermann et al., (2002), "Receptor-mediated Immunoglobulin G Transport Across Mucosal Barriers in Adult Life: Functional Expression of FcRn in the Mammalian Lung," <u>J. Exp. Med.</u> , 196:303-310.

EXAMINER	DATE CONSIDERED
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FORM PTO - 1449		ATTORNEY DOCKET NO.: LEX-011
SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		APPLICANT(S): Gillies <i>et al.</i>
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EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C231	Strom et al., (1996), "Therapeutic Approach to Organ Transplantation", <u>Blackwell Science</u> , Chapter 36, pp. 451-456.
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	C233	Thommesen et al., (2000), "Lysine 322 in the human IgG3 CH2 domain is crucial for antibody dependent complement activation", <u>Mol. Immunol.</u> , 37(16):995-1004.
	C234	Wells, (1990), "Additivity of Mutational Effect in Proteins," <u>Biochemistry</u> , 29(37):8509-8517.
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